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Pesticide Fact Sheet Number 167
Formaldehyde and Paraformaldehyde

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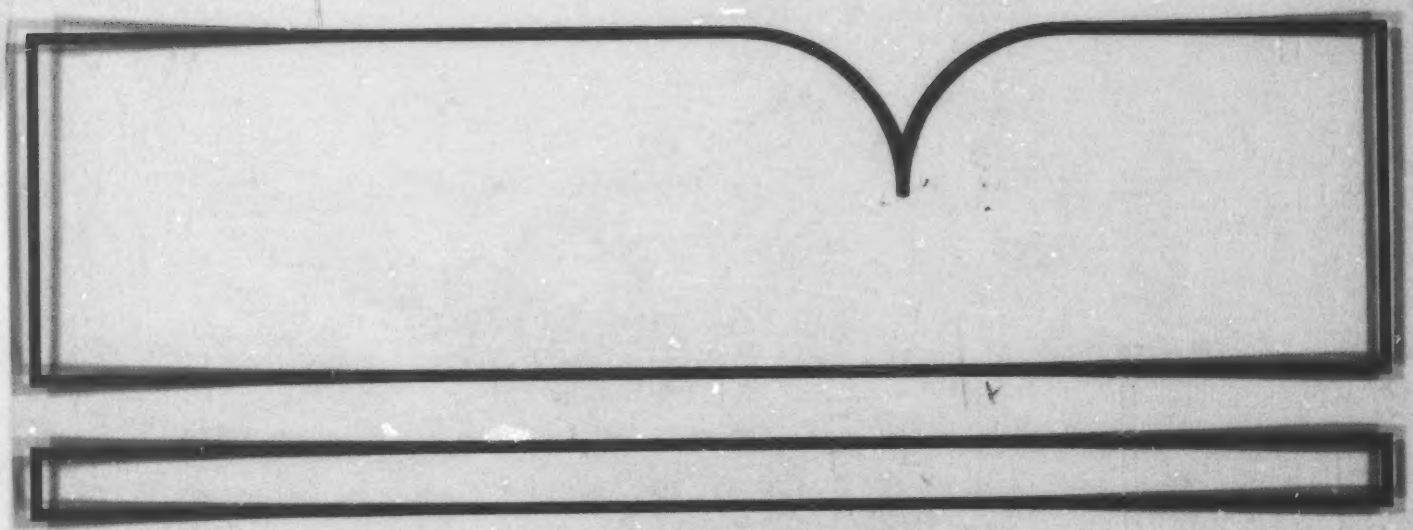

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

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EPA

Pesticide Fact Sheet

Name of Chemical: FORMALDEHYDE AND PARAFORMALDEHYDE
Reason for Issuance: REGISTRATION STANDARD
Date Issued: MAY 17,1988
Fact Sheet Number: 167

1. Description of Chemical

	FORMALDEHYDE	PARAFORMALDEHYDE
Generic Name	Formaldehyde	Paraformaldehyde
Common Name	Formic aldehyde, Methanal, Oxomethane, Oxymethylene, Methylene oxide, Formalin	Polyoxymethylene, Mixed polyoxy-methylene glycols
Trade Name	Formaldehyde Solution	Paraformaldehyde
EPA/OPP Pesticide Chemical Code	043001	043002
Chemical Abstracts Service (CAS) Number	50-00-0	30525-89-4
Year of Initial Registration	1948	1953
Pesticide Type	Disinfectant, Fungicide Microbiocide	Disinfectant, Fungi-cide, Microbiocide
Chemical Family	Aldehydes	Aldehydes

Description of Chemical (cont'd)

FORMALDEHYDE	PARAFORMALDEHYDE
U. S. & Foreign Producers	
Celanese Chemical Co., Inc.; Tenneco, Inc. E.I. duPont De Nemours & Co. Inc.; Georgia Pacific Corp., Monsanto Corp. and The Chemical Supply Co. (Great Britain)	Celanese Chemical Co., Inc., The Chemical Supply Company (Great Britain)

2. Use Patterns and Formulations

Application Sites:

Formaldehyde

Food and non-food crops; products for processing and industrial uses (e.g., drilling muds, metalworking cutting fluids and packer fluids); products for use on hard surfaces (e.g., livestock premises, household premises and contents, hospital critical equipment, transportation vehicles); fabrics and textiles (e.g., laundry, carpet); products for control of microbial pests associated with human and animal wastes (e.g., toilet bowls, urinals, diaper pails); and preservative of herbicidal, algaecidal, bacteriostatic, disinfectant, sanitizer, fungicidal and insecticidal formulations. There are 329 registered products that contain formaldehyde (46 products in which formaldehyde has always been considered as an active and 283 products in which formaldehyde was previously considered as an inert but has been redesignated as an active ingredient.)

Paraformaldehyde

Sugar maple tree tapholes; products for processing and industrial uses (e.g., secondary oil recovery systems, metalworking cutting fluids, oil recovery drilling muds and packer fluids); products for use on hard surfaces (e.g., kennels and pet animal quarters, livestock premises and equipment, household premises and contents, barber and beauty shop equipment and instruments); fabrics and textiles (e.g., laundry, mattresses, pillows and draperies); food handling establishment premise treatment; and preservative of bacteriostatic, algaecidal and fungicidal formulations. There are 119 registered products that contain paraformaldehyde (44 products in which the paraformaldehyde has always been considered as active and 75 products in which the paraformaldehyde was previously considered as an inert but has now been redesignated as an active ingredient.)

Number of Products

	Active Ingredient	Formerly Designated Inert Ingredient
Formaldehyde	46	283
Paraformaldehyde	44	75

Types of Formulations

Formaldehyde: gaseous, pelleted/tableted, soluble concentrate/liquid; 37%, 44% and 45% formulation intermediate/manufacturing use products. End use products range from less than 0.1% to 93%.

Paraformaldehyde: crystalline, wettable powder/dust, pelleted/tableted. There are not any registered manufacturing use products. End use products range from less than 0.1% to 100%.

Types and Methods of Applications

Formaldehyde

Spray (pump/electrical); dip; mop; brush; swab; sponge; automatic metering; proportioning pump; automatic pressure vaporizer; fumigation by (a) wet sheet method (b) addition of product to permanganate of potash in a bucket raised off of floor, and (c) fog application with electrical sprayer or mechanical fogging equipment.

Paraformaldehyde

Dip/immerse; proportioning pump; jet mixer; manual insert; fumigation by (a) hanging product in desired location, (b) generator, (c) application from electric hotplate, (d) placement of tablets in open dish and (e) placement of opened bottle in cabinets.

Application Rates

Formaldehyde

Seed treatment - Dosage rates = 1 pt 37%/30-40 gal. water; 37 lb/pt. - 40 gal. water.

Bacteriostatic - Dosage rates = 100 ppm-21,800 ppm.

Mold/mildew control - Dosage rates = 337 ppm-27,400 ppm.

Algae, bacteria and fungi control - Dosage rates = 1 ppm-1580 ppm.

Sanitizer - Dosage rates = .3 ppm - 2750 ppm.

Disinfectant - Dosage rates = 2 ppm - 370,000 ppm.

Paraformaldehyde

Bacteria control - Dosage rates = 2 ppm - 9010 ppm.

Mold/mildew control - Dosage rates = 4.9 ppm - 301 ppm.

Sanitization - Dosage rates = 6.4 ppm.

Disinfectant - Dosage rates = 2.9 ppm - 6.7 ppm.

3. Science Findings

Formaldehyde has been found to be carcinogenic in animal studies and there is limited evidence of carcinogenicity in humans. The Agency classified formaldehyde as a B1 oncogen. It is estimated that the worker risk from use of formaldehyde as an ingredient in an agricultural pesticide formulation is less than 10^{-6}. Areas of uncertainty exist in dietary exposure and exposure from other uses as an active ingredient, many of which are non-agricultural.

Chemical Characteristics:

	Formaldehyde	Paraformaldehyde
Physical State:	Gas	Crystalline, Wettable powder/Dust, Pelleted/Tableted
Odor:	Pungent	Pungent
Boiling Point:	-19.5°C(-3°F)	NA(technical is solid at room temp.)
Melting Point:	NA(gas at room temp.)	64°C
Unusual Handling Characteristics:	Corrosive to metal	

Toxicology Characteristics:

Most of the toxicological information on formaldehyde is from published sources. The toxicity of paraformaldehyde is believed to be identical to that of formaldehyde because it is the solid polymer of formaldehyde. The Agency does not have access to the raw data supporting these studies. Therefore, none of the studies (published and/or unpublished) is adequate for FIFRA regulatory purposes. However, based on these partially satisfactory studies, the following toxicological characteristics of formaldehyde and paraformaldehyde are expected.

Formaldehyde

Acute oral toxicity:
Toxicity Category 3; LD_{50} = 800mg/kg (rat)

Acute dermal toxicity:
Toxicity Category 3; LD_{50}>2g/kg

Acute inhalation toxicity:
Toxicity Category 3;
Lowest lethal concentration = 250 ppm (4hr. exposure)

Primary eye irritation: Toxicity Category 1

Formaldehyde (continued)

Primary skin irritation: Toxicity Category 2

Major route of exposure: inhalation, dermal

Paraformaldehyde

Acute oral toxicity
Toxicity Category 3; LD_{50}>1.6 g/kg (rat)

Acute dermal toxicity:
Toxicity Category 3; LD_{50}>2 g/kg

Acute inhalation toxicity:
Toxicity Category 1; LC_{50} about 14 ppm

Primary eye irritation: Toxicity Category 1

Primary skin irritation: Toxicity Category 2

Major route of exposure: inhalation, dermal

Chronic feeding and oncogenicity

Formaldehyde has been found to be carcinogenic by inhalation in rats, and there is evidence suggestive of carcinogenicity in mice. A recent drinking water study with formaldehyde showed evidence of carcinogenicity in the rat stomach. The Agency is requiring oral oncogenicity testing. Chronic toxicity testing (rodent and non-rodent) is also being required.

Developmental Toxicity

Inhalation studies in animals and epidemiological studies in workers have not demonstrated teratogenic effects. Teratogenicity studies in the rat and rabbit are required.

Reproduction

In one study, prolonged diestrus, but no impairment of reproductive function was reported. A 2 generation rat study is required.

Mutagenicity

Formaldehyde has caused genetic changes in Drosophila larvae, fungi, bacteria and mammalian cells. It is believed that formaldehyde is a weak mutagen and that it operates by some type of genetic interaction. Gene metabolism, structural chromosomal aberration and other genotoxic effects data are required.

General Metabolism

Formaldehyde is a normal metabolite in mammalian systems. In dogs, cats,

rabbits, guinea pigs and rats, the half life of formaldehyde is estimated to be one minute. General metabolism studies are not required.

Risk assessment results

It is estimated that the worker risks from use of formaldehyde as an ingredient in an agricultural pesticide formulation are $<10^{-6}$. Further estimates of the dietary risk and risk to workers from agricultural and non-agricultural uses will be conducted when the requested data are received.

Physiological and Biochemical Behavioral Characteristics:

Data are not available.

Environmental Characteristics:

There are no data available to assess the environmental fate of formaldehyde or paraformaldehyde. Data are not available to assess the ground water contamination potential for pesticidal uses of formaldehyde or paraformaldehyde. Also, formaldehyde was not included in the Agency's Data-Call-In Notice for potential ground water leachers. Degradation, metabolism, mobility, dissipation and accumulation studies are required. Indoor inhalation exposure reentry studies are required.

Ecological Characteristics:

Freshwater species:

LC_{50} = 100 ppm - bluegill sunfish

LC_{50} = 118 ppm - rainbow trout

Freshwater invertebrates

LC_{50} = 14 ppm - Daphnia magna (Water flea)

Marine and estuarine organisms

96 hr. LC_{50} = 69.1 ppm - Trachinotus carolinus (Florida pompano)

96 hr. LC_{50} = 69 ppm - Menidia menidia (Atlantic silversides)

96 hr. LC_{50} = 18 ppm - Roccus saxatilis (Striped bass)

EC_{50} = 1.8 ppm - Crassotrea virginica (Eastern oyster)

LC_{50} = 143 ppm - Panaeus duorarum (Pink shrimp)

Terrestrial species:

Acute oral LD_{50} = 790 mg/kg - mallard ducks

Terrestrial species (continued)

LC_{50}>5000 ppm - bobwhite quail and mallard ducks

A potential hazard may exist to marine and estuarine species from the use of formaldehyde in secondary oil recovery systems and other industrial effluents containing formaldehyde and use of paraformaldehyde in oil well drilling muds. Monitoring of formaldehyde levels in waters receiving residues from the use of the pesticide in secondary oil recovery systems and other industrial effluents (formaldehyde) and oil well drilling muds (paraformaldehyde) is required.

Four use patterns may possibly pose a risk to aquatic endangered and nonendangered species - use of formaldehyde on turf and the use of products containing formaldehyde and paraformaldehyde that are discharged as industrial effluents into shallow or enclosed bodies of water, use of formaldehyde in secondary oil recovery systems and use of formaldehyde in oil well drilling muds. However, risk to aquatic species cannot be characterized at this time because the Agency lacks pertinent chemical and exposure data which are being required.

Tolerance Assessments

No tolerances have been established for residues of formaldehyde or paraformaldehyde in or on plant or animal commodities, with the exception of a food additive tolerance of 2 ppm for residues of formaldehyde in maple syrup resulting from use of paraformaldehyde in maple tree tapholes (21 CFR 193.330.)

Formulations containing 1% or less of formaldehyde and 2% or less of paraformaldehyde are exempt from the requirement of tolerances when used as preservatives in pesticidal formulations applied to growing crops [40 CFR 180.1001(d)].

Formaldehyde is exempt from the requirement of a tolerance for residues in or on the grains of barley, corn, oats, sorghum, and wheat and the forages of alfalfa, Bermuda grass, bluegrass, brome grass, clover, cowpea hay, fescue, lespedeza, lupines, orchard grass, peanut hay, peavine hay, rye grass, soybean hay sudan grass, timothy and vetch resulting from postharvest application of formaldehyde or a mixture of methylene bispropionate (MBP) and oxy(bismethylene)bispropionate (OBMP) when used as a fungicide. These raw agricultural commodities are for use only as animal feeds (40 CFR 180.1032).

Paraformaldehyde is exempt from the requirement of a tolerance for residues in or on sugar beets (roots and tops) when applied to the soil not later than planting (40 CFR 180.1024).

The food additive tolerance (21 CFR 193.330) and current exemptions from the requirements of tolerances (40 CFR 180.1032, 180.1024 and 180.1001(d) are not supported due to the inadequacy of available data. Plant metabolism data along with storage stability data are required. If

residues of concern are found in plants, then residue data on crops are required. If residues are found in feed commodities, then livestock feeding studies must be submitted.

An acceptable daily intake (ADI) has not been established for formaldehyde. When the requested toxicological data are received, an ADI will be established. Based on requested residue data, a tolerance reassessment will be performed.

4. Summary of Regulatory Position and Rationale

- Formaldehyde and paraformaldehyde are pesticidally active when used in formulations as a preservative. Label ingredient statements must be revised to include the name and percentage of either when used as a preservative.

- Because the formaldehyde and paraformaldehyde exert their pesticidal effect only in the formulation, and do not affect the efficacy of the product itself, the label must include a statement to this effect.

- Formaldehyde and paraformaldehyde are not being placed in Special Review. Risks to workers using formulations containing these chemicals as preservatives are less than 1×10^{-6}, which does not warrant Special Review. The Agency lacks data on other uses of formaldehyde and paraformaldehyde to assess dietary and non-agricultural risks.

- Protective equipment (respirators) and other risk reduction measures are required for fumigation uses.

- Applications for new registration of products containing formaldehyde or paraformaldehyde must include exposure data to enable the Agency to perform a risk assessment.

- Endangered species labeling will not be required at this time. Four use patterns--turf use, products that are discharged into shallow or enclosed bodies of water, secondary oil recovery systems, and oil well drilling muds--may pose a risk, but the Agency lacks information needed to calculate the environmental concentrations and risks.

- While data gaps are being filled, products containing formaldehyde and paraformaldehyde may continue to be sold and distributed, provided that product labeling is revised as specified in the Registration Standard.

5. Summary of Major Data Gaps

Study	Due Date
Residue Chemistry	
Metabolism	18 months
Residues (Analytical Method)	15 months
Storage Stability	15 months
Environmental Fate	
Hydrolysis	9 months
Photodegradation	9 months
Metabolism	27 months
Leaching & adsorption/desorption	12 months
Volatility	12 months
Dissipation	27 months
Rotational crops (confined)	39 months
Ecological Effects	
Avian Single Dose Oral LD_{50} (Paraformaldehyde only)	9 months
Avian Dietary LC_{50} -upland game bird & water fowl (Paraformaldehyde only)	9 months
Aquatic Organism Testing	9-15 months
Special Test	
Residue Monitoring	12 months
Toxicology	
Acute studies	9 months
Mutagenicity tests	9-12 months
Dermal penetration	12 months
90 day feeding (rat & dog)	15-18 months
21 day dermal (rabbit)	15 months
90 day inhalation (rat)	15 months
Chronic toxicity (rat & dog)	50 months
Oral oncogenicity (rat & mouse)	50 months
Teratogenicity (rat & rabbit)	15 months
Reproduction (rat)	39 months
Re-entry	
Inhalation exposure	27 months

6. Contact Person at EPA

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